

# **EXHIBIT 38**

The TIRF REMS Access Program: Frequently Asked Questions

**TIRF REMS Access Program Frequently Asked Questions (FAQs)**

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The TIRF REMS Access Program: Frequently Asked Questions

## I. ALL STAKEHOLDERS FAQs

### What is a TIRF Medicine?

TIRF medicines are transmucosal immediate release fentanyl prescription medicines used to manage breakthrough pain in adults with cancer who are routinely taking other opioid (narcotic) pain medicines around-the-clock for pain. [Click here to see a full list of TIRF medicines.](#)

### What is a REMS?

REMS stands for “Risk Evaluation and Mitigation Strategy.” A Risk Evaluation and Mitigation Strategy (REMS) is a risk management program required by the FDA to ensure that the benefits of a drug outweigh the risks. FDA has determined that a REMS is necessary for all marketed TIRF medicines.

### What are the goals of the TIRF REMS Access Program?

The goals of the TIRF REMS Access program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

1. Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
2. Preventing inappropriate conversion between fentanyl products.
3. Preventing accidental exposure to children and others for whom it was not prescribed.
4. Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

### What are the components of the TIRF REMS Access program?

Because of the risk for misuse, abuse, addiction, and overdose, TIRF medicines are available only through a restricted program called the TIRF REMS Access program.

An overview of the requirements for prescribers, patients, pharmacies, and distributors is included below:

- **Healthcare providers** who prescribe TIRF medicines for outpatient use must review the prescriber educational materials, enroll in the REMS program, and commit to comply with the REMS requirements.
- **Patients** who are prescribed TIRF medicines in an outpatient setting, must understand the risks and benefits of the drug and sign a Patient-Prescriber Agreement Form with their healthcare provider to receive TIRF medicines. These patients will be enrolled by the pharmacy at the time their first prescription is filled.
- **Outpatient pharmacies** that dispense TIRF medicines for outpatient use must enroll in the program, train their pharmacy staff on the REMS requirements, and agree to comply with the REMS requirements. Pharmacy staff can register online to access the Education Program and take the Knowledge Assessment for training purposes.
- **Inpatient pharmacies** that dispense TIRF medicines for inpatient use must enroll in the Program, train their pharmacy staff on the REMS requirements, and agree to comply with the REMS requirements. Pharmacy staff can register online to access the Education Program and take the Knowledge Assessment for training purposes.
- **Wholesalers and distributors** that distribute TIRF medicines must enroll in the program and commit to distributing only to authorized enrolled pharmacies.

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The educational materials referenced above will be available to prescribers and pharmacies through the TIRF REMS Access program. In an outpatient setting, FDA-approved Medication Guides will be provided to patients by prescribers and pharmacists during counseling about the proper use of TIRF medicines.

**Inpatient Use Only-** Prescribers who prescribe TIRF medicines that will only be used in an inpatient setting (e.g., hospitals, hospices, or long-term care facilities) are not required to enroll in the TIRF REMS Access program. Similarly, patients who receive TIRF medicines in an inpatient setting are not required to enroll in the TIRF REMS Access program. Long term care and hospice patients who obtain their medications from outpatient pharmacies must be enrolled.

### **Why does the TIRF REMS Access program require prescriber enrollment for outpatient prescribing?**

Prescriber enrollment is required to help ensure that prescribers receive education on the risks and safe use of TIRF medicines, and can demonstrate their understanding of how to mitigate the risks. Additionally, the educational materials will help them understand the requirements of the TIRF REMS Access program.

To become enrolled, prescribers must review the TIRF REMS Access Education Program including the Full Prescribing Information and successfully complete the Knowledge Assessment.

### **Are there requirements for prescribers for inpatient use in the TIRF REMS Access program?**

No. Healthcare providers who prescribe TIRF medicines for inpatient use only are not required to enroll in the TIRF REMS Access program.

### **Why does the TIRF REMS Access program require pharmacy enrollment?**

Pharmacy enrollment is required to help ensure that pharmacists receive education on the risks and safe use of TIRF medicines. Additionally, the educational materials will help them understand the requirements of the TIRF REMS Access program.

Only enrolled pharmacies are eligible to receive shipments of TIRF medicines and/or to dispense prescriptions written by enrolled prescribers for outpatients. A designated authorized pharmacist must review the Education Program and successfully complete the Knowledge Assessment. Only then can the authorized pharmacist complete enrollment on behalf of the pharmacy. The authorized pharmacist will train other staff within the pharmacy in the appropriate dispensing of TIRF medicines according to the TIRF REMS Access program.

Prescriptions for outpatient use written by prescribers who are not enrolled in the REMS will not be authorized by the TIRF REMS Access program and TIRF medicines will not be dispensed to an outpatient who is not enrolled.

### **Why does the TIRF REMS Access program require a Patient-Prescriber Agreement Form?**

The TIRF REMS Access program requires all prescribers to complete and sign a TIRF REMS Access Patient-Prescriber Agreement Form with each new patient, before writing the patient's first TIRF prescription. The Patient-Prescriber Agreement Form helps to ensure that each patient for whom the TIRF medicine has been prescribed is appropriately counselled on the safe

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use and storage of the TIRF medicine. The prescriber must keep a copy of the signed Patient-Prescriber Agreement Form in the patient's chart, give a copy to the patient and submit a copy to the TIRF REMS Access program within 10 working days.

A Patient-Prescriber Agreement Form is not required for inpatient use of TIRF medicines

### **Where do I find a list of local pharmacies that participate in the TIRF REMS Access program?**

The TIRF REMS Access homepage contains a feature called "Pharmacy Lookup" that is available for prescribers, and distributors, to look up and find enrolled pharmacies. This information can also be obtained by calling the TIRF REMS Access call center at **1-866-822-1483**.

### **How can I obtain TIRF REMS Access program materials?**

All TIRF REMS Access education materials and forms are available and can be downloaded from [www.TIRFREMSAccess.com](http://www.TIRFREMSAccess.com) using Adobe Acrobat Reader. Enrollment Forms and the Patient-Prescriber Agreement Forms can be completed online at [www.TIRFREMSAccess.com](http://www.TIRFREMSAccess.com) after reviewing the Education Program and successfully completing the Knowledge Assessment. Materials are also available by calling the TIRF REMS Access call center at **1-866-822-1483** for assistance.

### **How do I contact the TIRF REMS Access program?**

You can contact the TIRF REMS Access program by calling the TIRF REMS Access call center at **1-866-822-1483** or by written correspondence to: TIRF REMS Access, PO Box 29036, Phoenix, AZ 85038

### **How can I report Adverse Events?**

Promptly report suspected adverse events associated with the use of a TIRF medicines including misuse, abuse, and overdose directly to the TIRF REMS Access program at **1-866-822-1483**. You also may report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088 or by mail using Form 3500, available at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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## **II. PATIENT FAQs**

### **As a patient, how do I participate with the TIRF REMS Access program?**

You must sign a Patient-Prescriber Agreement with your prescriber and take your prescription for a TIRF medicine to an 'enrolled' pharmacy. The pharmacy will enroll you in the TIRF REMS Access program. Your prescriber will go over important information you need to know before you take the TIRF medicine.

Patients in an inpatient setting are not required to participate in the TIRF REMS Access program in order to be prescribed and dispensed TIRF medicines for inpatient use only. However, if your prescriber gives you a prescription for a TIRF medicine to take at home once you leave the inpatient facility, you must sign a Patient-Prescriber Agreement Form with your prescriber to participate in the TIRF REMS Access program.

### **Where do I find a list of local pharmacies that participate in the TIRF REMS Access program?**

Only pharmacies that are enrolled in the TIRF REMS Access program can dispense TIRF medicines. Your prescriber can help you find a participating pharmacy. You can also get this information by calling the TIRF REMS Access program at **1-866-822-1483**.

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### **III. OUTPATIENT PHARMACY FAQs**

#### **What type of Outpatient Pharmacy is my pharmacy?**

There are 3 types of outpatient pharmacies. They are all required to be enrolled in the TIRF REMS Access program, complete the TIRF REMS Education Program, and verify patient and prescriber enrollment when processing prescriptions. The difference is in how these pharmacies enroll in the program.

**Independent Outpatient Pharmacy:** Retail, mail order or institutional outpatient pharmacies having an authorized pharmacy representative that is responsible for ensuring enrollment and training of the pharmacy staff within an individual outpatient pharmacy. Each store will individually enroll in the TIRF REMS Access program as a single pharmacy location.

**Chain Outpatient Pharmacy:** Retail, mail or institutional outpatient pharmacy having a chain headquarters that is responsible for ensuring enrollment and training of the pharmacy staff of all associated outpatient pharmacies. The chain headquarters will enroll multiple pharmacy locations (i.e.: chain stores) in the TIRF REMS Access program.

**Closed System Outpatient Pharmacy:** Institutional or mail order outpatient pharmacies that uses a pharmacy management system that does not support the process of electronically transmitting the validation and claim information currently required by the TIRF REMS Access program. If you believe you are a closed system outpatient pharmacy, call the TIRF REMS Access program call center at 1-866-822-1483 to discuss enrollment.

#### **How does an Independent Outpatient Pharmacy enroll in the TIRF REMS Access program?**

The authorized pharmacist must review the Education Program, successfully complete the Knowledge Assessment and complete the Independent Outpatient Pharmacy Enrollment Form through the website or complete and fax the signed Enrollment Form and Knowledge Assessment to the TIRF REMS Access program at **1-866-822-1487**.

The authorized pharmacist must ensure the pharmacy enables their pharmacy management system to support communication with the TIRF REMS Access system, using established telecommunication standards, and run the standardized validation test transactions.

Before a pharmacy is able to dispense prescriptions to outpatients, an enrollment form must be received either via the website by faxing or mailing it to the TIRF REMS Access program for each pharmacy requesting enrollment in the program. (See information on chain outpatient pharmacy enrollment below.)

#### **How does a Chain Outpatient Pharmacy enroll in the TIRF REMS Access program?**

An authorized chain outpatient pharmacy representative completes the TIRF REMS Access training, Knowledge Assessment and enrollment on behalf of all the pharmacies within the chain and then documents and manages training of all pharmacy staff by the chains' internal processes. Pharmacy staff can register online to access the Education Program and take the Knowledge Assessment for training purposes.

As part of enrollment, a chain outpatient pharmacy must enable the pharmacy management system to support communication with the TIRF REMS Access system, using established

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telecommunication standards, and must run the standardized validation test transactions. For further information or to enroll, access the TIRF REMS Access website at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) or call the TIRF REMS Access program call center at **1-866-822-1483** for further assistance.

### **How does a Closed System Outpatient Pharmacy enroll in the TIRF REMS Access program?**

If you believe you are a closed system outpatient pharmacy, call the TIRF REMS Access program call center at **1-866-822-1483** to discuss enrollment.

### **How long is my enrollment effective in TIRF REMS Access?**

Your enrollment is effective for two (2) years. You will be required to re-enroll in the TIRF REMS Access program every two (2) years if you wish to continue dispensing these products. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

Independent outpatient pharmacies and chain outpatient pharmacies may re-enroll online or by fax. Closed system outpatient pharmacies may re-enroll by fax only.

For re-enrollment online, go to the “Enrollment Activity” tab on the TIRF REMS Access program website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)). The “Enrollment Activity” tab allows you to:

- Add to, update, or delete your registration information on file.
- Review the TIRF REMS Access Education Program.
- Take the TIRF REMS Access Knowledge Assessment.
- Submit your enrollment form by providing your attestation and signature.

For re-enrollment by fax, review the TIRF REMS Access program Education Materials and submit a new TIRF REMS Access Enrollment Form and Knowledge Assessment to the TIRF REMS Access program at 1-866-822-1487. All TIRF REMS Access Education Materials and Enrollment Forms are available and can be downloaded from [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) using Adobe Acrobat Reader or by calling the TIRF REMS Access call center at **1-866-822-1483**.

### **If the patient’s prescription is denied, will the TIRF REMS Access system explain the reason?**

All TIRF prescriptions (excluding inpatient use), must go through an electronic verification system via the pharmacy management system. When a prescription is denied, an appropriately coded message will be displayed on the pharmacy management system. For assistance, please call the TIRF REMS Access call center at **1-866-822-1483** for any information related to your denial.

### **How does a pharmacy obtain TIRF Medicines from a distributor?**

Only enrolled distributors are allowed to distribute TIRF medicines to enrolled pharmacies. The TIRF REMS Access program provides frequently updated lists of all pharmacies that are currently enrolled in the program that distributors can use to verify enrollment before distributing TIRF medicines to a pharmacy.



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## **Chain and Independent Outpatient Pharmacy CASH Claim FAQs**

### **What is the definition of a TIRF REMS CASH Claim?**

The definition of a TIRF REMS CASH Claim is any claim for a TIRF medicine that is not electronically transmitted to a Third Party Insurance BIN using the pharmacy management system and established telecommunication standards. This includes claims for patients without prescription coverage or any paper claims submitted to a program for payment.

### **Does a TIRF REMS CASH claim need to be submitted to the TIRF REMS Access Program?**

Yes, all TIRF prescriptions, including CASH claims and other claims (i.e. workers comp), must be submitted to the TIRF REMS Access program to validate the enrollment status of the prescriber, patient and pharmacy prior to dispensing TIRF medicine to the patient.

### **How do I submit a TIRF REMS CASH claim to the TIRF REMS Access Program?**

Prior to dispensing TIRF medicines, transmit using the REMS CASH BIN 014780, to submit a CASH claim to the TIRF REMS Access program.

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#### **IV. PRESCRIBER FAQs**

##### **What is the enrollment process?**

The prescriber must review the Education Program, successfully complete the Knowledge Assessment and complete an enrollment form through the website at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com), or complete and fax the signed Enrollment Form and Knowledge Assessment to the TIRF REMS Access program at **1-866-822-1487**.

A prescriber may obtain an enrollment form online from the TIRF REMS Access website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)) or by calling **1-866-822-1483**.

The program requires that a signed enrollment form and Knowledge Assessment be received by the TIRF REMS Access program for each prescriber who requests enrollment. Only healthcare providers who will prescribe TIRF medicines for outpatient use are required to be enrolled in the TIRF REMS Access program.

##### **How long is my enrollment effective in TIRF REMS Access?**

Your enrollment is effective for two (2) years. You will be required to re-enroll in the TIRF REMS Access program every two (2) years if you wish to continue dispensing these products. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

You may re-enroll via your “Enrollment Activity” tab on the TIRF REMS Access program website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)). The “Enrollment Activity” tab allows you to:

- Add to, update, or delete your registration information on file.
- Review the TIRF REMS Access Education Program.
- Take the TIRF REMS Access Knowledge Assessment.
- Submit your enrollment form by providing your attestation and signature.

Alternatively, you may also complete re-enrollment via fax by reviewing the TIRF REMS Access program Education Materials and submitting a new TIRF REMS Access Enrollment Form and Knowledge Assessment into the TIRF REMS Access program at 1-866-822-1487. All TIRF REMS Access Education Materials and Enrollment Forms are available and can be downloaded from [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) using Adobe Acrobat Reader or by calling the TIRF REMS Access call center at **1-866-822-1483**.

##### **Where do I find a list of local pharmacies that participate in the TIRF REMS Access program?**

A list of participating pharmacies can be found on the TIRF REMS Access website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)) homepage under the link “Pharmacy Lookup”. You may also call **1-866-822-1483**.

Patients can find a participating pharmacy by calling the TIRF REMS Access program at **1-866-822-1483**.

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**Can I write an order for TIRF Medicines for inpatient use?**

Yes, prescribers can write orders for TIRF medicines for inpatient use without the prescriber or the patient being enrolled in the TIRF REMS Access program. However, the inpatient pharmacy needs to be enrolled in the TIRF REMS Access program to receive and dispense TIRF medicines to inpatients in the healthcare facility.

If a prescriber is discharging a patient with a TIRF medicine prescription, intended to be filled by an outpatient pharmacy, then the prescriber must be enrolled in the TIRF REMS Access program and complete a Patient-Prescriber Agreement Form. The prescription for outpatient use can only be filled through an enrolled outpatient pharmacy.

Additional information on the TIRF REMS Access Education Program and enrollment can be obtained through the TIRF REMS Access program ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)) or by calling **1-866-822-1483**.

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## **V. INPATIENT PHARMACY FAQs**

### **How do I enroll as an inpatient pharmacy?**

To enroll, the inpatient pharmacy must designate an authorized pharmacist who will review the required Education Program and successfully complete the Knowledge Assessment for the TIRF REMS Access program. Upon successful completion of the Knowledge Assessment, the authorized pharmacist will complete and sign the Inpatient Pharmacy Enrollment Form through the website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)). The Knowledge Assessment and Enrollment Form may also be completed, signed, and faxed to the TIRF REMS Access program at 1-866-822-1487.

Additional information about the TIRF REMS Access Education Program and enrollment can be obtained through the TIRF REMS Access program ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)) or by calling **1-866-822-1483**.

### **How long is my enrollment effective in TIRF REMS Access?**

Your enrollment is effective for two (2) years. You will be required to re-enroll in the TIRF REMS Access program every two (2) years if you wish to continue dispensing these products. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

You may re-enroll via your “Enrollment Activity” tab on the TIRF REMS Access program website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)). The “Enrollment Activity” tab allows you to:

- Add to, update, or delete your registration information on file.
- Review the TIRF REMS Access Education Program.
- Take the TIRF REMS Access Knowledge Assessment.
- Submit your enrollment form by providing your attestation and signature.

Alternatively, you may also complete re-enrollment via fax by reviewing the TIRF REMS Access program Education Materials and submitting a new TIRF REMS Access Enrollment Form and Knowledge Assessment into the TIRF REMS Access program at 1-866-822-1487. All TIRF REMS Access Education Materials and Enrollment Forms are available and can be downloaded from [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) using Adobe Acrobat Reader or by calling the TIRF REMS Access call center at **1-866-822-1483**.

### **Can inpatient pharmacies obtain TIRF Medicines in a Healthcare Facility?**

Yes. However, the inpatient pharmacy within or associated with the healthcare facility must be enrolled in the TIRF REMS Access program before inpatient pharmacies can purchase TIRF medicines.

Additional information can be obtained from [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) or by calling the TIRF REMS Access call center at **1-866-822-1483**.

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## **VI. DISTRIBUTOR (WHOLESALE) FAQs**

### **Does a distributor have to enroll in the TIRF REMS Access program?**

Yes, distributors will need to enroll in the TIRF REMS Access program in order to be able to purchase and distribute TIRF medicines.

### **How long is my enrollment effective in TIRF REMS Access?**

Your enrollment is effective for two (2) years. You will be required to re-enroll in the TIRF REMS Access program every two (2) years if you wish to continue dispensing these products. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

You can complete re-enrollment via fax by submitting a new TIRF REMS Access Enrollment Form into the TIRF REMS Access program at 1-866-822-1487. TIRF REMS Access Enrollment Forms are available and can be downloaded from [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) using Adobe Acrobat Reader or by calling the TIRF REMS Access call center at **1-866-822-1483**.

### **What are the TIRF REMS Access program requirements for a distributor?**

To enroll in the TIRF REMS Access program, a distributor will have to complete and sign the Distributor Enrollment Form. In signing the enrollment form, the distributor is required to indicate that they understand that TIRF medicines are available only through the TIRF REMS Access program and they will comply with the program requirements.

### **How can enrolled distributors access a list of pharmacies that participate in the TIRF REMS Access program?**

After enrollment, distributors can access the current list of enrolled pharmacies by:

- Downloading from a secure FTP site (you will be contacted regarding the TIRF REMS Access secure FTP site once your enrollment is complete).
- Utilizing the feature "Pharmacy Look Up" on a password protected section of the TIRF REMS Access website ([www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com))
- Calling the TIRF REMS Access call center at **1-866-822-1483**.